Version 03/09/21 (Add. #3)

NCI National Clinical Trials Network

EAF151

ECOG-ACRIN cancer research group
Reshaping the future of patient care

For Patients with Recurrent Glioblastoma

EAF151 Available Through ECOG-ACRIN Cancer Research Group

Change in Relative Cerebral Blood Volume as a Biomarker for Early Response to Bevacizumab in Patients with Recurrent Glioblastoma

Patient Population

See Section 3.0 for Complete Eligibility Details

- Age ≥ 18 years, Karnofsky PS ≥ 60, and adequate lab values
- Histologically proven intracranial glioblastoma or gliosarcoma at initial surgery
  - ◊ Patients will be eligible if the original histology was low-grade glioma and a subsequent diagnosis of glioblastoma/gliosarcoma is made
- Patient must not be pregnant or breast-feeding
- Progression of disease assessed by local site using RANO criteria, with plan to administer bevacizumab or its biosimilars either as single therapy or in conjunction with other chemotherapeutic/immunotherapy regimens, in order to treat tumor progression/recurrence
  - ◊ Patients receiving bevacizumab or biosimilar primarily for reduction of edema are excluded
- Must not have previously received a bevacizumab-containing regimen or its biosimilars
- For patients with intratumoral hemorrhage, there must be at least 10 x 10 x 10 mm "measurable enhancement" that is not obscured/distorted by magnetic susceptibility blooming artifact
- Progressive enhancement on MRI within 28 days of registration, and ≥ 42 days since completion of standard radiation/temozolimide therapy (adjuvant temozolimide is allowable)
- Must be cleared for administration of bevacizumab or its biosimilars with respect to recent surgeries, and post-surgical scans must confirm the presence of measurable residual disease
- Must be able to tolerate brain MRI scans with gadabutrol (see protocol for additional MRI eligibility details)
- Must be scheduled for treatment regimen with bevacizumab or biosimilar (alone or in combination with other chemotherapies/immunotherapies); may receive treatment with Optune

Study Design/Imaging

See Sections 5.0 and 9.0 for Complete Study Design Details

- Patient registration occurs per protocol, then baseline DSC-MRI is performed prior to bevacizumab or biosimilar initiation (within 3 days), preferably on same day for patient convenience
- Initial dose of bevacizumab or biosimilar is given
- Patient returns for follow-up DSC-MRI before the 2nd dose of bevacizumab; the DSC-MRI can occur between 12-25 days after the initial bevacizumab or biosimilar infusion
- Second dose of bevacizumab or biosimilar is given
- Follow-up on patients will continue for up to 5 years, or until 1 year past last enrolled participant, whichever occurs first

Notes (refer to EAF151 Site Imaging Manual):

- *If the routine imaging performed by the local site includes EAF151 DSC-MRI protocol + standard brain tumor imaging protocol (BTIP), then this satisfies the baseline perfusion imaging requirement and no additional baseline imaging is needed (see Section 9)*
- *If a patient with normal/near normal renal function has consented to participate in the exploratory test-retest study, and there is adequate time before bevacizumab or biosimilar initiation, a second baseline DSC-MRI will be performed with identical protocol and preferably on the same scanner at least 48 hours apart from the first baseline DSC-MRI*
- *Sites will be required to undergo scanner qualification prior to subject enrollment*
  - ◊ *The use of contrast media on qualification scans is recommended, but not mandatory*
  - ◊ *1.5T or 3T scanner (excluding low-field and 7T scanners) can be used*

Study Chair:
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Co-Chair:
Kathleen Schmainda, Ph.D.

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN), https://open.ctsu.org

Protocol Information

ECOG-ACRIN Operations - Boston: 857-504-2900, http://ecog-acrin.org (Member Login)

Please Enroll Your Eligible Patients!

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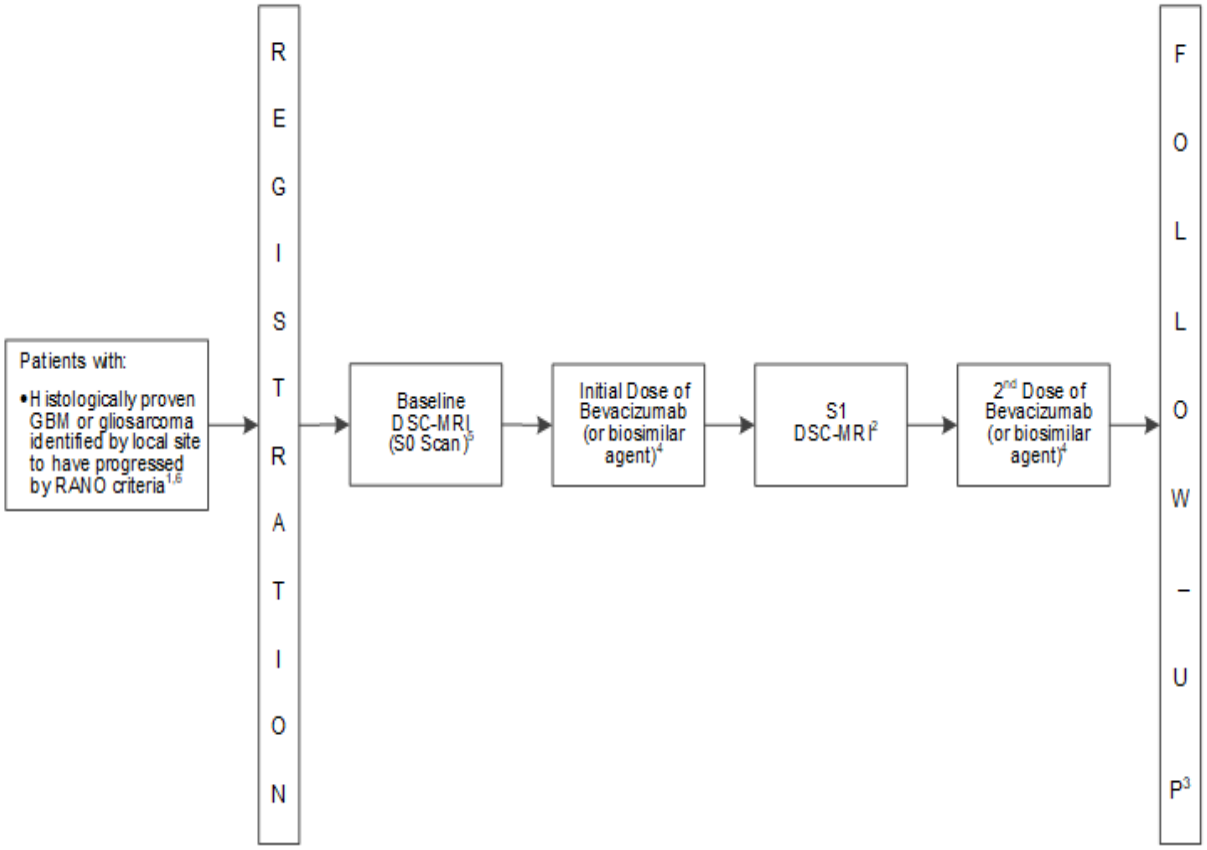
Schema



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1. Requirements for recurrent GBM: a) any progression in a patient who has not previously received a bevacizumab containing regimen, b) imaging upon which local site decision is made must be recent (within 28 days of registration) and demonstrate progressive contrast enhancement (>25% increase from nadir in contrast enhancing volume or new measurable contrast enhancing lesion remote from the primary site) with measurable enhancement defined as two perpendicular in-plane diameters of at least 10 mm and at least 10 mm in the 3rd orthogonal direction.
2. S1 DSC-MRI can be completed 12-25 days after initial dose of bevacizumab (or biosimilar agent) and before the 2nd dose of bevacizumab (or biosimilar agent) is given to the patient.
3. All patients will be followed to up to 5 years or one year after last patient is enrolled, whichever occurs first.
4. Bevacizumab (or biosimilar agent) may be combined with other chemotherapies, immunotherapies or Optune.
5. Baseline scan may be done prior to registration per Section 9.2.
6. If the patient's most recent recurrence occurs while on immunotherapy, this must be judged as true recurrence using iRANO criteria.